RECOMMENDATION

Covid-19 Treatment Review and Advisory Working Group (CTRAWG)

Re: Sotrovimab

30NOV2021

The CTRAWG in collaboration with the evidence review expertise of the Covid Therapeutics Committee (CTC) has reviewed the evidence and practical use parameters for Sotrovimab treatment for Covid-19 infected patients in reducing hospitalizations and risk of death and applied the Ethical Framework for Allocating Scarce Drug Resources During the COVID-19 Pandemic to develop the following recommendation:

Sotrovimab should be used in accordance with the CTC "Clinical Practice Guide for the use of Sotrovimab in Patients with COVID-19" who are within 7 days of onset of symptoms and have no prior history of COVID-19 infection:

A. In Communities
    a. High risk outpatient population who have a medical risk factor that would limit the immune response to vaccination OR
    b. Unvaccinated or partially vaccinated individuals AND
    c. Are mildly ill with symptoms of confirmed COVID-19 infection, AND
    d. Who are at high risk of developing severe COVID-19-related complications.

B. For Inpatients
    a. Use in outbreak situations from a nosocomial infection with COVID-19 and,
    b. High risk individuals who have a medical risk factor that would limit the immune response to vaccination OR
    c. Unvaccinated or partially vaccinated individuals, AND
    d. Are mildly ill with symptoms of confirmed COVID-19 infection, AND
    e. Are at high risk of developing severe COVID-19-related complications.

CTRAWG with support from CTC will continue to monitor supply and new evidence as they evolve to update this recommendation as necessary.

Sincerely,

Richard Jones RPh, ACPR, FACHE

Chair CTRAWG

Companion Document: "Clinical Practice Guide for the Use of Sotrovimab in Patients with Covid-19"

BC COVID THERAPEUTICS COMMITTEE (CTC)

Clinical Practice Guide for the Use of Sotrovimab in Patients with COVID-19

RECOMMENDATION

Sotrovimab can be CONSIDERED for adults and children 12 years or older (≥ 40kgs) who are **mildly ill** from confirmed COVID-19 (see #1), AND:

- Who are outpatients OR inpatients within a nosocomial outbreak, AND
- Who can receive Sotrovimab **within 7 days of symptom onset** (see #2), AND
- Who have **at least 1 risk factor*** for disease progression such as (see #3):
    - age 55 years or older
    - diabetes mellitus treated with medication
    - obesity (BMI >30 kg/m^2)
    - chronic kidney disease (eGFR, <60 mL/min)
    - congestive heart failure (NYHA class II, III, or IV)
    - chronic respiratory conditions such as COPD or moderate to severe asthma

    *These risk factors comprise trial inclusion criteria. Other significant risk factors or comorbidities may also be used at the discretion of the clinician (e.g. immunocompromise, auto-immune diseases etc.), AND
- Who are **inadequately vaccinated** against COVID-19 (see #4), i.e.:
    - **Unvaccinated or partially unvaccinated** (received 0 or 1 of 2 COVID-19 vaccine doses) with no prior history of COVID-19 infection, OR
    - **Unlikely to adequately respond to vaccination** despite two** COVID-19 vaccine doses due to:
        - Active treatment for solid tumor or hematological malignancies, OR
        - Having received a solid organ transplant and treated with immunosuppression, OR
        - Receiving CAR-T cell therapy or hematopoietic stem cell transplant in the last 2 yrs, OR
        - Having a moderate to severe primary immunodeficiency, OR
        - Having advanced untreated HIV or AIDS, OR
        - Active receipt of anti-B cell therapies (e.g. rituximab, ocrelizumab, obinutuzumab), high-dose systemic steroids (=20mg prednisone equivalent daily for at least 14 days), alkylating agents (e.g. cyclophosphamide, cisplatin), antimetabolites (e.g. methotrexate, 5-FU) or anti-TNF agents (e.g. infliximab, adalimumab)

        **Such patients, upon receipt of a third dose of a COVID-19 vaccine may or may not adequately respond to vaccination. Case-by-case evaluation with an expert is recommended.

Dose: **500mg IV x 1 dose of sotrovimab.** There are insufficient data to recommend the IM route[2] (see #5).

Patients should be informed that sotrovimab does not have full Health Canada approval for this indication and consent should be obtained (see #6).